CLIA UPDATE
Individualized Quality Control Plans (IQCP) & Regulation Updates

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Topics for Discussion

- CLIA Data
- Status of CMS/CDC Regulations
  - PT Revisions
  - Patient Access
- IQCP Implementation
- Resources

Current Statistics-Enrollment

Total Number of Laboratories	**232, 996**
Total Non-Exempt	**225,879**
– ***Compliance***	19,354
– ***A ccredited***	15,658
– ***Waived***	153,568
– ***Provider Performed Microscopy***	37,299
– ***Exempt***	***7117***
• *NY*	3,518
• *WA*	3,599

CMS data base 7/2012

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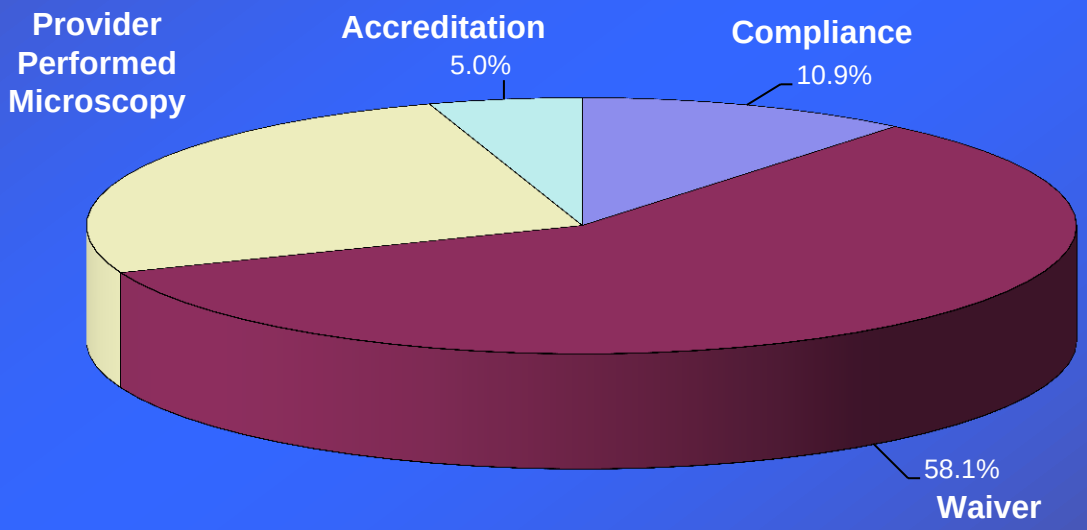
Current Statistics

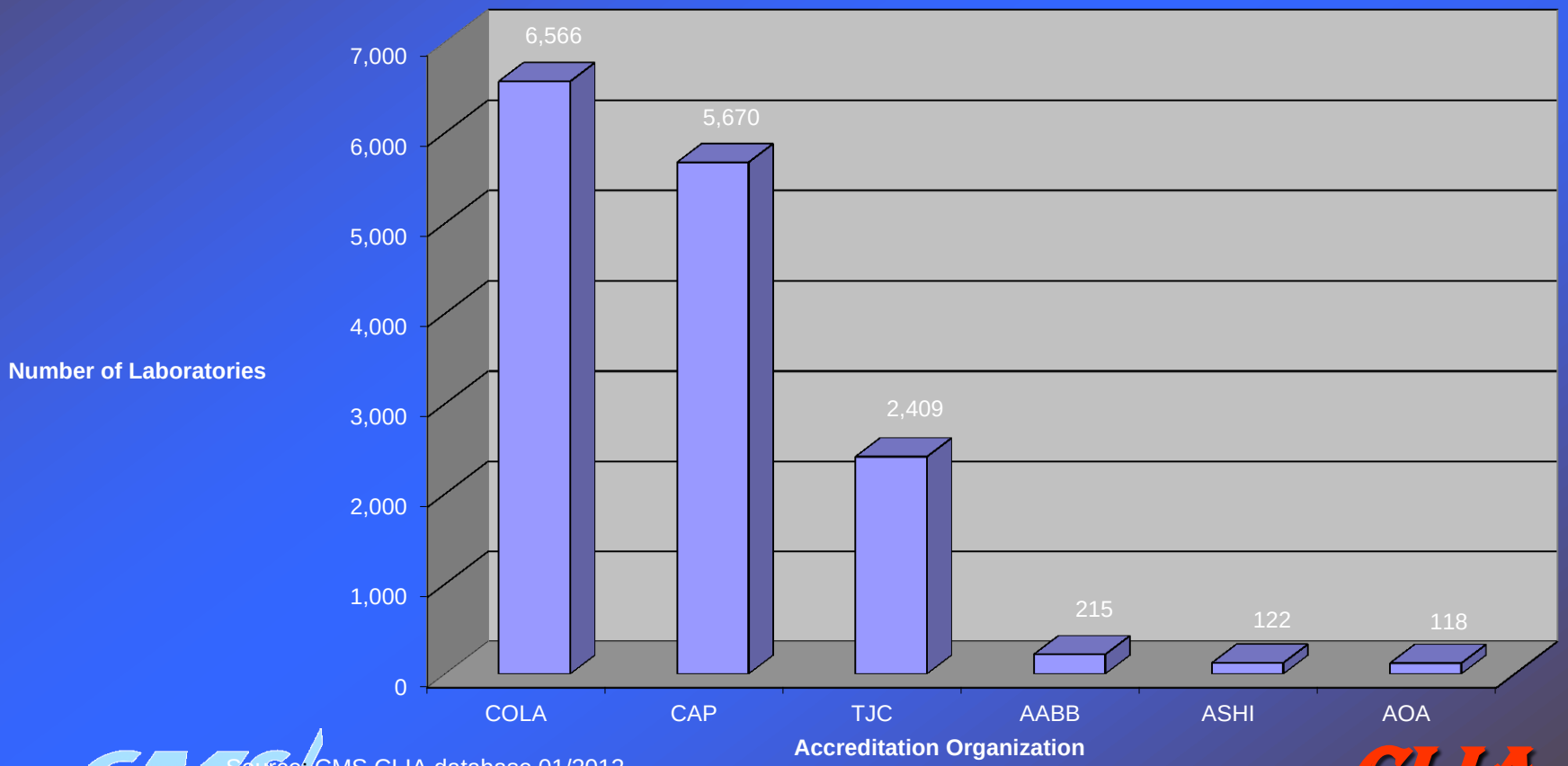
Physician Office Laboratories
by CLIA Certificate Type
(Non-Exempt Only)



Source: CMS CLIA database

Current Statistics

Number of CLIA Certificate of Accreditation Laboratories by Accreditation Organization



Source: CMS CLIA database 01/2012

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Future of CLIA & EHR's Proposed Patient Access Rule

- Standards, practices & technology for electronic exchange of lab information are still evolving.
- CMS will revisit CLIA Interpretive Guidelines, to ensure laboratories & stakeholders have clear guidance on best practices/resources to implement Health Information Technology.
- Proposed rule for patient access to laboratory results published 9/12/11 by CMS, CDC & OCR. Comments analyzed; final responses developed.

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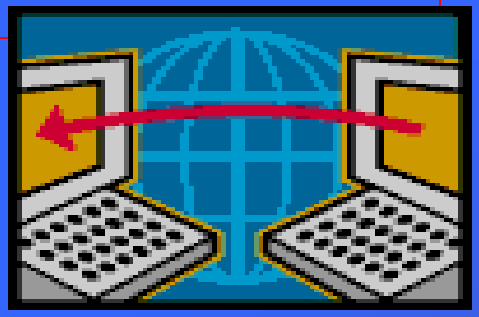
Helpful EHR Links



- **Health Information Technology**
  - http://healthit.gov/portal/server.pt
- **CLIA EHR S&C package**
  - http://www.cms.gov/SurveyCertificationGenInfo/PMSR/list.asp#TopofPage
- **OCR Posting of Security Breaches**
  - http://www.hhs.gov/ocr/privacy/hipaa/administrative/breachnotificationrule/postedbreaches.html
- **FDA Safety Portal**
  - https://www.safetyreporting.hhs.gov

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PT Regulation Update

- Plan w/ milestones developed; no firm ETA
  - Includes: test selection, target values, grading criteria, PT programs, labs, PT referral
  - Requires a proposed rule w/ comment & final
- CLIAC recommended to proceed
  - CLIAC WG w/ SMEs from affected parties
  - 1st PT providers' meeting held; 2nd Mar. 2012
  - Method for test selection identified
- Add'l data used to determine grading criteria & target values

PT Referral Update

DO NOT SEND PT SAMPLES TO ANOTHER LABORATORY!!

- CMS Central Office continues to review all cases
- Reflex, confirmation, distributed, referral testing seem to be major causes
- Common personnel across several laboratories/health systems contribute
- Guidance--
  - For Now: Read & Follow CMS PT Brochure
  - For Future: Expect regulatory changes; legislative proposals

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Background & History of CLIA Quality Control

- CLIA Law passed—1988
- Final CLIA Regulations published—1992
  - 5 basic QC requirements—mod. complexity
    - Follow manufacturer's instructions
    - All QC actions acceptable—phase in
  - All requirements apply to high complexity
- Many expert meetings convened by CDC/CMS to no avail
- Quality System Regulations pub.—2003
  - Updated all QC requirements

2003 Regulations--Inception of EQC

- New provision for alternative QC in CMS' Interpretive Guidelines (IG) in lieu of changing regulations w/ new technology, as long as "equivalent quality testing" is provided--- *42 CFR 493.1250 & 1256(d).*
- Default: 2 levels external QC/day of testing
- Equivalent QC or 'EQC' developed in IG as a voluntary alternative QC--2004

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EQC Follow Up

- Concerns expressed by industry, laboratories, experts, etc.
- Many laboratories adopted EQC successfully & have no quality issues; but no flexibility
- CMS reached out to CLSI to facilitate development of an scientific, objective consensus QC guideline

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QC for the Future

- CLSI convened the well-attended ‘QC for the Future’ meeting in 2005
- Sponsored by accrediting orgs., industry, professional orgs. & gov’t. agencies
- Outcome:
  - Stakeholder concern that manufacturers don’t provide labs sufficient information
  - ‘One-size-fits-all’ QC doesn’t work w/ new technology

Designing The "Right QC"

- CLSI meeting directed the development of Evaluation Protocol (EP)-23—Laboratory Quality Control Based on Risk Management
  - Chaired by James Nichols, PhD—Baystate Health
  - Assembled expert group
  - Published October, 2011

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The "Right QC" is IQCP

- CMS will incorporate key EP-23 concepts into CLIA Interpretive Guidelines (IG) as an acceptable QC policy called IQCP

The "Right QC" is IQCP

- Applies to CMS-certified non-waived labs
- Covers all phases of testing process, not just QC
- May or may not reduce QC amt. or frequency
- IQCP is optional
- Default is regulation - 493.1256(d)(3)
- Includes existing & new analytes/test systems & specialties, except cytology/histopathology

The "Right QC" is IQCP

- Permits labs to develop an IQCP using their existing quality practices/information
  - E.g., test verification data is a start
- Considers known risks mitigated by mfgr. &
- Formalizes laboratories' risk mgt. decisions

The "Right QC" is IQCP

- Can be customized based on labs' patient pop., environment, test system, personnel, test uses
- Offers flexibility to achieve QC compliance for each test
- Adaptable to future technology advancements

The "Right QC" is IQCP

- Once effective, IQCP will supersede the current EQC policy
- Existing CLIA QC & quality system concepts won't change
- No regulations will change!
- CMS' outcome oriented survey won't change
- Labs must also follow mfr's. instructions
- Lab director has overall responsibility for QCP

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Education & Transition Period for IQCP – Laboratories

- There'll be an education & transition period for labs before IQCP is fully effective

Info and Guidance will be provided to labs

www.cms.hhs.gov/clia/

For Questions: **IQCP@cms.hhs.gov**

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Education & Transition Period for IQCP - Laboratories

In the interim, CMS certified labs should:

- Continue to follow existing QC protocols
- Learn about EP-23 concepts & IQCP
- Plan & complete their transition accordingly
  - Phase out EQC (if using it)
  - Decide to implement default QC or IQCP

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Education & Transition Period for IQCP

- CMS will notify labs of important dates:
  - Beginning of transition & education period
  - End of education & transition period
- At the end, labs must be in compliance w/ their QC choice
- Or deficiencies will be cited

Education & Transition Period for IQCP

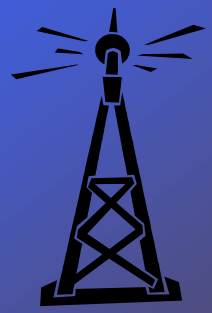
- CMS will solicit accrediting orgs (AO) to determine their interest in IQCP

- Accredited labs should continue to meet their accrediting org.'s QC standards until they receive notice from their AO

Education & Transition Period for IQCP

- No control procedure regulatory citations will be issued prior to the end of the education & transition period unless serious test quality problems are found

- Please stay tuned…..



Where to Obtain Information

CMS/CLIA Web site:

www.cms.hhs.gov/clia/

IG, Brochures, app, IQCP Info

CMS CLIA Central Office:

410-786-3531

Judy Yost's Email:

Judith.yost@cms.hhs.gov

IQCP Link:

IQCP@cms.hhs.gov

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IQCP is the Right QC!!

THE END!!

Thank You!!!

Questions????